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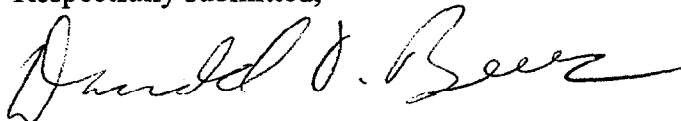
Dockets Management Branch  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20857

**Re: Petition for Stay; NDA 20-932**

Dear Sir or Madam:

On behalf of Roxane Laboratories, Inc., the applicant for the above-referenced new drug application, we petition the Food and Drug Administration to stay the effective date of that new drug application under 21 C.F.R. 10.35. We request that the stay be until such time as Roxane Laboratories submits additional data, FDA has reviewed those data and has determined that those data support the conclusion that the drug covered by the application has been shown to be safe and effective, and the labeling for the drug has been revised to reflect those data. We understand that the revised labeling will make it clear that neither the applicant nor FDA rely, in the determination that the drug covered by the NDA is safe and effective, on any investigations as to which Roxane does not have a right of reference. It is understood that the drug covered by the NDA will not be marketed during the pendency of the stay.

Respectfully submitted,



Donald O. Beers

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